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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,313	07/25/2005	Yasukazu Nagato	P26361	8640

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,313	NAGATO ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/25/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement dated 7/25/05 and the preliminary amendments to the claims dated 12/10/04 is hereby acknowledged.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) has been considered. However, parts of the information disclosure statement filed 7/12/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the non-patent literature citations that have *not* been initialed on the PTO-1449 are not accompanied with a translation or English abstract. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for suppressing side effects caused by antitumor agents, does not reasonably provide enablement for inhibiting hair loss with or without use of an antitumor agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill Of those in the art,

7) the predictability of the art, and 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art.

The claimed invention relates to a composition for suppressing the side effects caused by antitumor agents and inhibiting hair loss, which encompasses both normal hair loss, hair loss caused different skin diseases such as alopecias and hair loss as a side effect caused by antitumor agents. Various antitumor agents having various degrees of side effects including different degrees of hair loss cannot be totally inhibited by a single composition. Given the great diversity between normal hair loss (hair loss due to end of life span of the hair follicle, hair loss due to pregnancy and labor, hair loss due to psychological stress, hair loss due to covering hair permanently in some cultures, etc.), hair loss caused by various drugs that may be used as chemotherapy let alone radiotherapy which causes local hair loss too according to the site of administration. The unpredictability of using this composition has a number of facets, as discussed hereinafter. These claims are reach through claims, as various conditions may or may not need chemotherapy or radiotherapy may be unlikely inhibiting hair loss by the specific composition disclosed.

Treatment of Disease Type:

While the state of the art is relatively high with regard to the treatment and reducing of hair loss with a specific agent, it is long underdeveloped with regard to the inhibition of hair loss such as in cases of alopecia. The composition is a general treatment, with no specified disease. In particular, there is no known drug that can **inhibit** totally each and every hair loss disorder and/or hair loss related to chemotherapy and radiotherapy.

Thus, a considerable amount of empirical testing is required, with no a priori expectation of success being present, before claiming inhibiting a specific symptom of a disease, such as, hair loss, which may happen for physiological reasons.

2. The breadth of the claims:

The claims are very broad and inclusive generally "inhibiting hair loss" and "inhibiting hair loss caused by the use of an antitumor agent", which includes any etiology of hair loss plus the use of any antitumor agent or radiotherapy. Clearly, the compositions are only used to treat diseases, in which, providing a pharmaceutical compound of claim 1, and 2, offers improvement for hair loss but not inhibiting hair loss.

3. The amount of direction or guidance provided and the presence or absence of workinq examples:

The specification provides no direction for ascertaining, a priori, which types of hair loss is specifically inhibited, except hair loss caused by antitumor agents.

4. The quantity of experimentation necessary:

The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art. Applicants fail to provide the guidance and information required to ascertain which particular hair loss disorders the claimed agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the inhibition of hair loss is not sufficient to justify claiming inhibiting hair loss and/or inhibiting hair loss caused by antitumor agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07233061 A. JP 07233061 A expressly discloses a mixture of straight-chain L-lactic acid condensate having 3-25 degree of condensation and L-lactic acid cyclic condensate have 2-15 degree of condensation which is mixed in food additive or dissolved in water (Abstract). The method by which the condensates are prepared does not appear to patentably distinguish the present composition claims from the prior art compositions and the intent of use would not also impart patentability to the instant claims since the prior art composition could have been able to accomplish the same use.

2. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10-130153 to Youichirou et al (based on entire document).

JP 10-130153 discloses an anti-malignant tumor agent useful for cancer selected from colon cancer, esophagus cancer, and breast cancer. The anti-malignant tumor agent comprises a cyclic and straight-chain mixed with poly L-lactic acid having a 3-19 degree condensation as the main component. The agent is mixed with other carriers to

provide an oral composition (liquid, capsules, or powder), see paragraph 0012 and paragraph 0019.

Claim 5 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695,698,227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of JP 07233061 or JP 10- 130153.

The two references have been discussed hereinabove in relation to the instant claims. Neither of the references disclosed literally that the composition is used for inhibiting hair loss in inhibiting hair loss caused by the use of antitumor agents.

The two references discloses that the composition is used for treatment of malignant tumor. The composition would inherently have the same effect on hair loss.

Accordingly, it would have been obvious to one of ordinary skill in the art to use the instant composition for reducing hair loss caused by the use of antitumor conventional drugs because the skilled man has already used the same composition for the same illness and it would be within his abilities to notice its effect in reducing hair loss while monitoring the patient's physical condition while being treated. The person with moderate skill in the art would have expected success in using the composition for treating hair loss and reducing side effects of antitumor drugs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18, 20-21, and 23 of U.S. Patent No. 6,734,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

US '214 is directed to a method of treating at least one of diabetes and complications arising from diabetes in a subject in need of such treatment, wherein the method comprises administering to the subject a therapeutically effective amount of a cyclic and/or linear poly lactic acids having a condensation degree of 3 to 19.

The method claims of '214 anticipates the instant claims since the method claims require the same agent as instantly claimed to practice the methodology of '241; thus one must necessarily have possession of the agent. With regard to the product-by-process claims, the method by which the condensate is prepared does not appear to patentably distinguish the instant agent and from the prior art. With regard to the composition claims, it should be noted that US '241 is directed to administering the agent and administration of an medicament implicitly requires the agent to be mixed in an excipient/vehicle to administer the medicament, which reads on "composition".

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
7/14/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER